Edward White Hospital

2323 9th Avenue North
P.O. Box 12018
St. Petersburg, Florida 33733-2018
Phone (727) 323-1111

December 22, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Re: Docket 2004D-0343
Guidance for Industry and FDA Staff: Hospital Bed System Dimensional Guidance to Reduce Entrapment

Thank you for the opportunity to comment on the FDA draft guidance: ***Hospital Bed System Dimensional Guidance to Reduce Entrapment.***

We understand and appreciate the intention of this document, to minimize the potential of patient entrapment in a hospital bed. But we feel that the introduction statement[3] and Appendix F will focus attention on proactive testing of existing beds with little or no actual risk reduction. In fact, this focus will stretch currently scarce resources that would be better spent on patient assessment and modification of the bed environment if warranted based on patient size and/or condition.

As written, this guidance will create an expectation of hospitals and long term care facilities inspecting all of their existing (legacy) hospital beds for compliance with these dimensional limitations. Our understanding is that pilot testing of existing beds has revealed that most if not all existing beds will not meet these dimensional limitations. So the extensive time and effort that will be required to determine that our 167 existing hospital beds will not pass is wasted with no risk reduction. The dimensional guidance has value to existing beds if it is clearly stated that the primary focus must first be clinical assessment of the patient physical condition to establish that they are vulnerable to the risk of bed entrapment. At that point, the focus of the clinical and support staff should be the assessment of the hospital bed system with a clear plan for addition or modification of that system to meet that specific patient's needs.

FDA must revise this draft document to clearly identify existing (legacy) beds are not inherently "unsafe" even though they do not meet the new dimensional limits established in this document. The focus on dimensional limits must be on new beds manufactured after the implementation of this document. The focus on legacy equipment is patient assessment first, with risk mitigation efforts based on meeting that patient's need.

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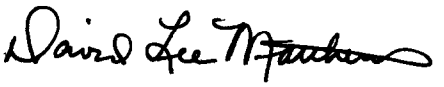
During my fifteen year career working in hospitals as Director of Facilities and Safety Officer, both profit and not-for-profit, I have no personal knowledge of any issues regarding bed entrapment. We have "Incident Reporting Systems" in place to identify issues and refer them to the appropriate individual. Clearly, if bed equipment were the issue I would know about the problem. Further, I attended an ASHE Seminar that specifically addressed the statistics of bed entrapment which supports my own experience. The need to test for an inherently "unsafe" condition will draw on my already limited resources. I very strongly urge you to reconsider this draft and make patient assessment the primary focus.

Currently my hospital assesses patients for fall risk. When appropriate specialty beds are used to reduced the potential for injury due to falls. The program has been successful in reducing falls in high risk patients. Similar risk assessment can be done for bed entrapment.

Sincerely,



David Lee Matthews, P.E., CHFM, SASHE

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[1] Bed entrapment occurs when a patient slips between the mattress and bed rail or when the patient becomes entrapped in the bed rail itself. Entrapment risk may increase when patients are frail or elderly or when patients have conditions that cause them to move about the bed or try to exit from the bed.

[2] The document states "...the FDA believes the risk of entrapment can be reduced through the development of new hospital bed or rail design configurations and **the assessment and modification of existing (legacy) hospital bed systems**". To review the document, go to **http://www.fda.gov/cdrh/beds/**

[3] "...the FDA believes the risk of entrapment can be reduced through the development of new hospital bed or rail design configurations and **the assessment and modification of existing (legacy) hospital bed systems**".